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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,388	06/11/2007	Fredrik Nicklasson	PCH0918USPCT	8119

27777 7590 04/13/2011

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EXAMINER	
WELTER, RACHAEL E	
ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
04/13/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/591,388	NICKLASSON ET AL.	
	Examiner	Art Unit	
	RACHAEL WELTER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/19/11*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgements

Receipt of the amendments and remarks/arguments filed on 1/19/11 is acknowledged.

Claim Status

Claims 16-26 are pending. Claims 1-15 are cancelled.

Withdrawn Rejections

The rejection of claim 26 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicant's amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 16-18 and 25-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Henley (US Patent No. 5,415,629; Published 5/16/1995) is maintained.

Henley teaches an apparatus for programmable iontophoretic or iontophoretic-ultrasonic transdermal delivery of medication across the skin or other biological membrane (abstract). Henley teaches that a passive transdermal delivery patch can be combined with a programmable, wearable ionosonic or iontophoretic drug delivery apparatus to improve medical management of pain, drug/substance detoxification, and many other illnesses (column 5, lines 58-64). The apparatus can be used to deliver nicotine among other drugs (column 5, lines 31-35). The device comprises a medicament carrying layer and an electrically conductive means electrically connected

to the medicament carrying layer (claim 1). There is a programmable means in the device for controlling the depth of penetration of medicament into the skin. In a preferred embodiment of the invention, the device is in the form of a band wherein the inner surface may be an adhesive, an open cell material, peptide-impregnated material, or other similar matrix (column 6, lines 14-18).

Although Henley suggests the use of nicotine in its devices, it is not immediately envisaged and therefore the instant rejection is made under obviousness.

It would have been obvious to an artisan of ordinary skill at the time the invention was made to look at the guidance provided by Henley and incorporate nicotine in the device. One would have been motivated to do so since Henley suggests the use of nicotine as a suitable alternative among medicaments administered. Furthermore, it is within the skill of an artisan to select a given medicament depending on the desired treatment and the particular needs of a patient population.

Regarding the limitation, where the first administration part (transdermal patch) is detachable from the second iontophoretic administration part, the examiner directs applicant to Figure 1 of Henley. The oscillator driver and iontophoretic driver (iontophoretic part) are separate from the electrode (transdermal part) and are attached via wires. Therefore, one would reasonably assume that the two administration parts would be detachable and that the device could be unwired and deconstructed.

Regarding the limitation where the device is occlusive, it is the examiner's position that Henley's transdermal delivery devices would exhibit such properties. It is noted that the instant invention has a thin aluminum layer in its device acting as a

barrier to nicotine diffusion through the backing material of its device (see instant specification pg. 14, lines 24-26). Henley also teaches a metallic foil on its electrode which comprises a flexible sheet forming a conductive matrix (column 7, lines 53-59). As such, it would be reasonable to assume that Henley's transdermal delivery devices would exhibit occlusive properties just like the instant invention.

Response to Arguments

Applicant's arguments filed 1/19/11 have been fully considered but they are not persuasive.

Applicant argues that they amended the claims to "wherein said first and second nicotine administration parts are combined in one unit." Applicant argues that the iontophoretic device and ionosonic device of Henley only corresponds to an embodiment of the second part of applicant's claimed device. While applicant submits Henley teaches combining the ionosonic programmable or iontophoretic drug device with a passive pain relieving patch for the short acting narcotic Fentanyl, applicant argues there is no teaching or suggestion in Henley of combining a passive and programmable device in one unit for the administration of nicotine as claimed and as described in the examples of the present application.

In response to applicant's arguments, the examiner directs applicant's attention to column 5, lines 56-68 of Henley.

> Fentanyl.RTM., a short acting narcotic, is currently commercially available as a passive patch for pain management. **Combining such a passive transdermal delivery system with the programmable, wearable ionosonic or iontophoretic drug delivery apparatus of the present invention will greatly improve the current medical management of pain, drug/substance detoxification, and many other illnesses currently managed by injections and repeated dosing of drugs.** Such **an apparatus**

provides a greatly improved method of drug delivery over the current timed release technology. Such technology incorporated into **a wearable apparatus** may ultimately replace birth control pills and require less dosing, produce less side effects, and be programmed to release ovulation suppressing hormones only at the critical times.

Henley refers to the combination of a passive transdermal delivery system with the ionosonic or iontophoretic drug delivery apparatus as a single, wearable apparatus. Thus, the reference seems to indicate that the transdermal patch and iontophoretic delivery are combined in one unit as recited in claim 16. Applicant has not structurally differentiated the instant claims from Henley. Applicant submits that Henley is different from the examples of the present application but applicant has not incorporated the alleged distinguishing features of the examples in the instant claims. Furthermore, the examiner is interpreting Henley's medicament carrying layer (see claims 1, 6-7 of Henley), which can be a polymeric matrix and porous material to be the first nicotine administration part and Henley's electrically conductive means as the second nicotine administration part.

Although applicant argues that the combination of a passive transdermal delivery system and iontophoretic drug delivery apparatus is not necessarily exemplified and a preferred embodiment of the invention, it should be noted that the rejections above are based on obviousness and not anticipation. Therefore, the criteria for establishing a case of prima facie obviousness is not whether the prior art exemplifies all the claimed limitations but whether the prior art suggests the claimed limitations. As acknowledged by applicant, Henley does suggest the combination of a first nicotine administration part and a second nicotine administration part. This is sufficient in establishing obviousness. Additionally, the examiner directs applicant's attention to MPEP 2123, II: "Disclosed

examples and preferred embodiments **do not constitute a teaching away form the broader disclosure** or nonpreferred embodiment".

Applicant further argues that Henley teaches away from combining a programmable device with a passive patch when delivering nicotine at column 4, lines 52-59.

However, the examiner respectfully disagrees with applicant that Henley is teaching away from a passive patch in column 4, lines 52-59. Henley is merely discussing the advantages of programmable dosing compared to passive delivery systems such as the nicotine patch. Although Henley might be teaching away from a passive transdermal drug delivery system by itself, Henley is not teaching away from the combination of a passive transdermal delivery system and iontophoretic drug delivery apparatus, which applicant is claiming. Applicant is directed to MPEP 2123. Henley does not explicitly criticize, discredit, or necessarily discourage the combination of transdermal delivery and iontophoretic delivery in a single unit. In fact, Henley later disloses that passive transdermal delivery can be combined with a programmable iontophoretic drug delivery in an apparatus. See the examiner's response above. Applicant is further reminded that "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed…." *In re Fulton,*391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

As such, it is the examiner's position that the rejection should be maintained for the reasons stated above.

The rejection of claims 19-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Henley (US Patent No. 5,415,629; Published 5/16/1995) as applied to claims 16-18 and 25 above and in further view of Hansson (US 2004/0191322; Published 9/30/04) is maintained.

The disclosure of Henley is discussed above.

Although Henley teaches that its devices can deliver nicotine, Henley does not explicitly teach that its devices deliver nicotine free bases, nicotine salts, nicotine inclusion complexes, or nicotine cation exchangers wherein nicotine is with polyacrylate.

Hansson teaches nicotine-containing compositions that can be administered by any convenient route including buccal, nasal, ocular, pulmonary, topical, or transdermal routes (paragraph 0050). The nicotine can be administered in the form of bases or salts wherein salts include nicotine tartrate and nicotine hydrochloride (paragraph 0046). Additionally, Hansson teaches that nicotine can be incorporated as cation exchange resin complexes with groups consisting of methacrylic containing carboxylic functional groups and inclusion complexes with cyclodextrin (paragraph 0004). According to Hansson, different salts, complexes, and combinations of nicotine bases/salts are used to achieve different release rates (paragraphs 0047-0048).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to incorporate different combinations as well as different forms of nicotine in each delivery aspect of Henley's delivery devices. One would have been motivated to do so since Hansson teaches that such nicotine forms are conventionally

used in transdermal devices. Furthermore, one would have been motivated to do so depending on the desired release rate or the needs of a particular patient population.

Response to Arguments

Applicant's arguments filed 1/19/11 have been fully considered but they are not persuasive.

Applicant argues that the teachings of Hansson do not make up for the deficiency in Henley and their combination fails to teach or suggest the claimed invention.

In response to applicant's arguments, the examiner directs applicant's attention to the examiner's response regarding Henley above, which is incorporated herein. Hansson is only cited for teaching different forms of nicotine in transdermal patches and applicant has not argued this teaching.

As such, it is the examiner's position that the rejection should be maintained for the reason stated above.

Conclusion

Claims 16-26 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL WELTER whose telephone number is (571)270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611